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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,783	12/08/2003	L. Dean Parks	1238.009	4821

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MELVIN K. SILVERMAN AND ASSOCS PC
500 WEST CYPRESS CREEK ROAD
SUITE 350
FT. LAUDERDALE, FL 33309

EXAMINER	
PERREIRA, MELISSA JEAN	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,783	PARKS, L. DEAN	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/4/10 has been entered.

2. Claims 11-16 are pending in the application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearlman et al. (WO/9918800).

5. Pearlman et al. (WO/9918800) discloses a topical composition comprising a pediculocide (i.e. ivermectin) with a pediculostatic agent (i.e. CETAPHIL ® cleanser) (abstract; p18, lines 9+; p19, lines 19-28). The levels of active ingredient (i.e. ivermectin) may be typically from about 0.25% to about 2.5% (p6, lines10-15).

6. Pearlman et al. further teaches that any commercially available product, such as cleansers, lotions, moisturizers, such as those that are non-toxic may be used as the pediculostatic agent, not excluding Cetaphil ® moisturizing lotion (Pearlman et al., p4, lines 29+; p17, lines 1-10; p13, lines 30+; p17, lines 1-10).

7. Pearlman et al. does not explicitly disclose Cetaphil ® moisturizing lotion as the pediculocide or explicitly disclose the concentration of ivermectin from about 0.05 to about 0.1% or 0.075% (w/v).

8. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the Cetaphil ® moisturizing lotion for the Cetaphil ® Cleanser as both products are produced by the same laboratories (Galderma Laboratories, Inc.) and Pearlman et al. teaches of the use of cleansers and lotions/moisturizers, such as those that are non-toxic interchangeably as a pediculostatic agent.

9. Also, at the time of the invention it would have been obvious to one ordinarily skilled in the art to include an active agent (i.e. ivermectin) in a concentration of from about 0.1%, etc. in combination with a CETAPHIL ® cleanser or CETAPHIL ® moisturizer as Pearlman et al. teaches of the concentration of typically from about 0.25% to about 2.5% where the concentration of typically from about 0.25% of Pearlman et al. encompasses the concentration of the instant claims of from about 0.1% and from about 0.075% as the higher and lower limits of the range of about 0.1% is not defined, for example.

10. The composition of the disclosure encompasses the dermatological composition of the instant claims and is capable of the same functions, such as not causing skin irritation of patients and has the same properties.

11. The intended use of the dermatological composition is not afforded any patentable weight. "The recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). The topical compositions of the combined disclosures encompass the dermatological composition of the instant claims and thus are capable of the same functions, such as treating transient acantholytic dermatitis, acne millaris necrotica, etc. and not causing skin irritation of patients and have the same properties.

Response to Arguments

12. Applicant's arguments filed 5/4/10 have been fully considered but they are not persuasive.

13. Applicant asserts that the present inventor has discovered that the combination of very low concentration of ivermectin with the specific medium as defined is particularly effective for treating the subject conditions. After daily use of the instant composition for up to several months no skin irritation, or increase of skin sensitivity was found. On the contrary, Pearlman's teaching is directed to a pediculostatic agent for elimination of head lice with a limited time of skin contact, in which the considerations on suitability and patient safety in treating those suffering from the dermatological conditions as defined in Claim 11 are complete absent.

14. The instant claims are not drawn to the method of administering the composition for treating the subject condition.

15. The composition of Pearlman et al. comprises a pediculocide (i.e. ivermectin) with a pediculostatic agent (i.e. CETAPHIL ® cleanser) wherein the substitution of Cetaphil ® moisturizing lotion for the Cetaphil ® Cleanser would have been obvious to one ordinarily skilled in the art as both products are produced by the same laboratories (Galderma Laboratories, Inc.) and Pearlman et al. teaches of the use of cleansers and lotions/moisturizers, such as those that are non-toxic interchangeably as a pediculostatic agent.

16. Applicant asserts that none of the preferred compositions taught by Pearlman et al. is designed for prolonged skin exposure, and not suitable for topical treatment for those suffering from the dermatological conditions as defined in the present invention. Applicant also asserts that the pediculocides active ingredients can be used at levels effective to achieve their intended results of treating head lice infestations, which are at a concentration from about 0.25% to about 2.5%.

17. The instant claims are not drawn to the method of administering the composition, for prolonged skin exposure or for treating the subject condition.

18. Pearlman et al. teaches that the pediculocidal active ingredient (i.e. ivermectin) can be incorporated into the pediculstatic formulation, ***typically from about*** 0.25% to about 2.5%. Therefore, it would have been obvious to one skilled in the art to vary/optimize the amount of pediculocidal active ingredient in the composition (Pearlman et al. p6, lines10-15).

19. The instant claims recites, "an avermectin compound in a concentration from about 0.05% to about 0.1%" wherein the amount ***typically from about*** 0.25% of ivermectin of Pearlman et al. encompasses the concentration range of from about 0.05% to about 0.1% of the instant claims as the higher and lower limits of the range of about 0.1% is not defined.

20. The topical compositions of the combined disclosures encompass the dermatological composition of the instant claims and thus are capable of the same functions, such as treating transient acantholytic dermatitis, acne millaris necrotica, etc. and not causing skin irritation of patients and have the same properties.

21. Applicant asserts that Pearlman et al.'s teaching of compositions containing multiple chemicals that are known to cause skin irritation (i.e. sodium lauryl sulfate, parabens, etc.) teaches away from the instant composition that requires being free of these chemicals and requires not causing skin irritation upon repetitive daily use.

22. Pearlman et al. teaches that the pediculostatic agent may comprise sodium lauryl sulfate or parabens but does not necessarily comprise sodium lauryl sulfate or parabens, etc. as Pearlman et al. states that the pediculostatic agent can ***optionally*** include other components, such as paraben preservatives (p5, lines 7-17; p16, lines 16+). Pearlman et al. teaches that the pediculostatic agent may comprise cleansers, lotions/moisturizers, creams, such as those that are non-toxic, honey, yogurt, etc. which do not include parabens, etc. (p4, lines 29+; p5, lines 30+; p17, lines 1-10).

23. Applicant asserts that Pearlman et al. teaches away from the present invention wherein the lowest ivermectin concentration of about 0.25% in Pearlman et al. is more

than double of the highest concentration in the instant composition. It is evident that Pearlman et al.'s teaching is only pertinent to a composition having a pediculostatic property. Pearlman et al. does not teach a composition that is suitable for treating subject clinical conditions without causing problems.

24. Pearlman et al. teaches that the pediculocidal active ingredient (i.e. ivermectin) can be incorporated into the pediculstatic formulation, ***typically from about*** 0.25% to about 2.5%.

25. The instant claims recites, "an avermectin compound in a concentration from about 0.05% to about 0.1%" wherein the amount ***typically from about*** 0.25% of ivermectin of Pearlman et al. encompasses the concentration range of from about 0.05% to about 0.1% of the instant claims, for example, as the higher and lower limits of the range of about 0.1% is not defined.

26. The topical compositions of the combined disclosures encompass the dermatological composition of the instant claims and thus are capable of the same functions, such as treating transient acantholytic dermatitis, acne millaris necrotica, etc. and not causing skin irritation of patients and have the same properties.

27. Applicant asserts that Pearlman's teaching of soaps, cleansers, lotions, moisturizers, conditions, etc. includes tens of thousands of commercial personal care and food products. Using the Examiner's rationale, all of these can be used interchangeably as pediculostatic agent to stun the lice. However, this is a different field from clinical treatment of dermatological conditions.

28. Pearlman et al. teaches the topical composition comprising a pediculocide (i.e. ivermectin) with a pediculostatic agent (i.e. CETAPHIL ® cleanser) and further teaches that any commercially available product, such as cleansers, lotions, moisturizers, such as those that are non-toxic, etc. may be used as the pediculostatic agent, not excluding Cetaphil ® moisturizing lotion. The intended use of the dermatological composition is not afforded any patentable weight.

29. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the Cetaphil ® moisturizing lotion for the Cetaphil ® Cleanser as both products are produced by the same laboratories (Galderma Laboratories, Inc.) and Pearlman et al. teaches of the use of cleansers and lotions/moisturizers, such as those that are non-toxic interchangeably as a pediculostatic agent.

30. The topical compositions of the combined disclosures encompass the dermatological composition of the instant claims and thus are capable of the same functions, such as treating transient acantholytic dermatitis, acne millaris necrotica, etc. and not causing skin irritation of patients and have the same properties.

31. Applicant asserts that Galderma Laboratories, Inc. produces hundreds of different commercial products, and each of them has its own composition, property and utility. Therefore, it is not obvious for one skilled in the art to substitute one product for another simply because the two products are made by the same company.

32. Pearlman et al. teaches the topical composition comprising a pediculocide (i.e. ivermectin) with a pediculostatic agent (i.e. CETAPHIL ® cleanser) and further teaches that any commercially available product, such as cleansers, lotions, moisturizers, such

as those that are non-toxic, etc. may be used as the pediculostatic agent, not excluding Cetaphil ® moisturizing lotion.

33. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the Cetaphil ® moisturizing lotion for the Cetaphil ® Cleanser as both products are produced by the same laboratories (Galderma Laboratories, Inc.) and Pearlman et al. teaches of the use of cleansers and lotions/moisturizers, such as those that are non-toxic interchangeably as a pediculostatic agent.

34. Applicant asserts that in Titanium Metals Corp of America vs. Banner, the claimed 0.8% nickel is between 0.75% and 0.9% shown by the reference, and the difference of the claimed nickel from the reference is 6% and 12.5%, respectively. As to the molybdenum, the claimed 0.3% molybdenum is also between 0.25% and 0.31% of molybdenum shown by the reference, and the difference of the claimed molybdenum from the reference is 15% and 3%, respectively. As to titanium, the claimed titanium is 98.8% which is between 99% and 98.75% shown by the reference, and the difference of the claimed titanium from the reference is 2% and 0.05%, respectively. This is substantially different from the present case. As discussed above, the lowest ivermectin concentration of about 0.25% in Pearlman et al. is more than double of the highest concentration in the instant composition. More specifically, the lowest concentration of 0.25% in Pearlman et al. is 150% higher than the highest concentration of 0.1% in the instant composition. Therefore, it is improper to construe that "about 0.1%" would overlap with a concentration that is 150% higher; and it is improper to construe a

concentration of "about 0.25%" would overlap or encompass a concentration that is less than its 50%.

35. Pearlman et al. teaches that the pediculocidal active ingredient (i.e. ivermectin) can be incorporated into the pediculstatic formulation, ***typically from about*** 0.25% to about 2.5%.

36. The instant claims recites, "an avermectin compound in a concentration from about 0.05% to about 0.1%" wherein the amount ***typically from about*** 0.25% of ivermectin of Pearlman et al. encompasses the concentration range of from about 0.05% to about 0.1% of the instant claims, for example, as the higher and lower limits of the range of about 0.1% is not defined.

Conclusion

37. No claims are allowed at this time.

38. This is a continuation of applicant's earlier Application No. 10/730783. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618
/Melissa Perreira/
Examiner, Art Unit 1618